

**PREHOSPITAL EMERGENCY SERVICES
LAY RESCUER AUTOMATED EXTERNAL DEFIBRILLATORS (AED)
REGULATIONS AND GUIDELINES**

Introduction

The following is a summary of the most recent and relevant information regarding Public Access Defibrillator (PAD) programs for use by lay rescuers. This material is provided as a resource and is not intended to take the place of advice from legal counsel. As the legal and regulatory landscape relating to PAD programs are complex and continue to change, we recommend that all members discuss and review the statutes, regulations, and guidelines with legal counsel to ensure best faith efforts to comply with the relevant statutes, regulations, and guidelines contained in this advisory.

The purpose of an AED program for lay rescuers is to provide that critical third link in the Chain of Survival by using an AED to prevent death from sudden cardiac arrest (SCA) prior to the arrival of EMS personnel.

Each Lay Rescuer Automated External Defibrillator Program will differ based on the size and needs of each entity. We have provided a list of useful links at the end of this advisory to direct you to sites that can provide valuable information regarding PAD program design and implementation consideration, including but not limited to, determining PAD locations, program team, placement, access and storage, training, documentation, communication, and decisions that will need to be made to ensure your PAD program succeeds.

Under California Civil Code § 1714.21, the state of California provides protection from civil damages to entities that acquire an AED for emergency use as long as the entity has complied with subdivision (b) of Section § 1797.196 of the Health and Safety Code. Individuals using an AED or performing CPR are protected from civil damages if they provide emergency care or treatment in good faith and do not expect compensation. These protections do not apply in the case of personal injury or wrongful death that results from the gross negligence or willful or wanton misconduct of the person who renders emergency care or treatment by the use of an AED.

In addition, regulations for Lay Rescuer AED program requirements, including training and use of AEDs for lay rescuers are set forth in the California Code of Regulations. The current *Public Access Automated External Defibrillator Regulations* has been in effect since 2003. The revised final regulation, with a title change to *Lay Rescuer Automated External Defibrillator Regulations* is expected to be in place, without any anticipated changes, by June 30, 2008.

Summary of Requirements

The summary of requirements in this advisory is based on the NEW 2008 revised regulations that are expected to become final by June 30, 2008. The recommendations are based on our research and best practices necessary to ensure the success and effectiveness of a public access AED program for lay rescuers. Entities that acquire and place one or more AEDs for employee and/or public use and access must:

1. Comply with all statutes and regulations governing Lay Rescuer AED regulation requirements including the training, use, placement, inspection, and maintenance of an AED.
2. Notify, in writing, the local EMS agency of the existence, location, and type of AED acquired, as well as other information that the local EMS service requires. This varies by county and by joint power authority (JPA) EMS entities.
3. Maintain and regularly test unit(s) according to guidelines set by
 - The manufacturer, **and**
 - The American Heart Association, **and**
 - The American Red Cross, **and**
 - Any applicable rules and regulations set by the FDA, **and**
 - Any other applicable state and federal authority
4. Check units for readiness
 - After each use, **and**
 - At least once every 30 days if it has not been used during that 30 days
 - Inspect every 30 days even if used
 - Document and maintain records of AED inspections
5. Develop a mechanism that ensures that when an AED is used
 - The Chain of Survival is part of your PAD program and is activated immediately.
 - Follow the Chain of Survival steps:
 1. Call 9-1-1 to activate the local EMS service
 2. Start early CPR
 3. Defibrillate within 5-7 minutes
 4. Ensure early advanced life support (ALS) upon arrival of the local EMS
 - Report use of AED to the medical director for review
 - Report the use of the AED to the local EMS agency

6. Provide training
 - To employees identified as lay rescuers on CPR and AEDs use
 - Based on the number of AEDs you acquire (purchase or donated)
 - 1-5 AEDs – one trained person for each of the five AEDs
 - 6-10 AEDs – one trained person for every five additional AEDs (when you obtain the sixth AED, train one more person)
 - To comply with the regulations
 - To meet the training topics and skills required by the California Emergency Medical Service Authority *Lay Rescuer Automated External Defibrillator Regulations* and the standards established by the American Heart Association or the American Red Cross

7. Develop a **written** plan
 - Describe procedures to be followed in the event of an emergency that may involve the use of an AED
 - Ensure compliance with statutory and regulatory requirements
 - Include Internal Emergency Response System procedures regarding activation of the "9-1-1" emergency system and for the access, coordination, and management of immediate medical care to seriously ill or injured individuals. This can be accomplished by updating your employee Emergency Action Plan (EAP) or by adding a separate section to the plan.

8. Select a Medical Director for your Lay Rescuer Automated External Defibrillator Program Oversight
 - Medical Director must be currently licensed in California as a physician and surgeon
 - The duties of a Medical Director are to
 - Ensure that each member who provides AEDs has a training program for their lay rescuers that meets the regulatory requirements
 - Review each incident that involved the use of an AED and ensure that quality improvement activities are taken, if indicated
 - Participate in developing an Internal Emergency Response Plan to ensure compliance with regulations for training, notification, and maintenance

Health and Safety Code § 1797.196 also states specific requirements for building owners who provide AEDs for use by their tenants in emergency situations and for principals of public and private K-12 schools who have units at their facilities.

Suggested Guidelines and Recommendations for Lay Rescuer AED Program Implementation

1. Know, understand, and incorporate California requirements for Lay Rescuer AED programs into your written program.
2. Know, understand, and incorporate your local county EMS or JPA Emergency Medical Services Lay Rescuer AED requirements into your written PAD program.
3. Consult with your legal advisors.
4. Consult with your risk manager.
5. Develop a team to evaluate your entity's "needs and wants" based on your specific workplace.
6. Select and work with AED vendors who can support your ongoing monthly inspection and maintenance program.
7. Create a written Lay Rescuer AED program for employee and/or public access to meet your specific needs and regulatory requirements.
8. Educate all employees about "sudden cardiac arrest."
9. Document equipment inspection, maintenance, and replacement program (batteries, electrodes, expiration dates, etc.). Determine how long you will you retain AED inspection and maintenance records. This is not addressed in the regulations or statutes.
10. Document any variance from AED "Good Samaritan" statutes.
11. Determine how long you will you retain AED incident reports. This is not addressed in the regulations or statutes.
12. Integrate AED program into existing Emergency Action Plans (EAPs) as part of the health and safety program.
13. Structure 3rd party relationships to allocate risk (manufacturers, suppliers, service vendors, etc.).
14. Understand the AED manufacturer's indemnification provisions.
15. Explore the availability of grants to purchase or upgrade AEDs.
16. Establish procedures for accepting donated AEDs and ensuring that they are operable.
17. Try your best to comply with the AED Good Samaritan immunity laws.
18. Prevent failure of your AED program by ensuring that you incorporate the following:
 - Inspect and maintain equipment. Make sure it works and inspect each AED every 30 days and after each use.
 - Place AEDs where they are easy to see and access.
 - Train and encourage employees to respond to emergencies
 - Educate all employees on the nature of Sudden Cardiac Arrest – People die if not defibrillated; prevent negligence to respond through training and education
 - Describe "Good Samaritan" immunity protection, and exceptions to immunity

Useful Links

Local Emergency Medical Services – ABAG PLAN Member Jurisdictions

- Alameda County Emergency Medical Services
http://www.acgov.org/ems/ems_PAD.htm
- Coastal Valley Emergency Medical Services (Napa, Sonoma, Mendocino Counties)
<http://www.sonoma-county.org/cvremis/>
- Marin County
<http://www.co.marin.ca.us/depts/hh/main/ems/index.cfm/>
- Solano County Emergency Medical Services Cooperative
<http://www.co.solano.ca.us/Department/Department.asp?NavID=583>
- San Mateo County Emergency Medical Services
http://www.co.sanmateo.ca.us/smc/department/home/0,2151,1954_291885143,00.html
- Santa Clara County Office of Emergency Services
<http://sscemsagency.org/prortal/site/ems>
- California State Emergency Medical Service Authority (EMS)
<http://www.emsa.cahwnet.gov/>

Implementation and Training Guidelines

- AED Risk Insights (Excellent resource)
www.aedriskinsights.com/resources.asp
- AED Implementation Guide - American Heart Organization
www.americanheart.org/downloadable/heart/110262192170770-2272%20AED%20ImplementGuide.pdf
- AED Implementation Guide Sample – One Beat at a Time
http://onebeatatathime.com/files/AED_Implementation_Guide.pdf
- The American Heart Association
<http://www.americanheart.org/presenter.jhtml?identifier=3011859>
- The American Red Cross
<http://www.redcross.org/services/hss/courses/aed.html>

- Food and Drug Administration – Heart Health Online Automated External Defibrillators - <http://www.fda.gov/hearthealth/treatments/medicaldevices/aed.html>

California Good Samaritan Statutes

- California Health and Safety Code Sections 1799.100 and 1799.102
<http://www.leginfo.ca.gov/cgi-bin/waisgate?WAISdocID=99030220511+0+0+0&WAIAction=retrieve>
- California Civil Code Sections 1714.2 and 1714.21
<http://www.leginfo.ca.gov/cgi-bin/displaycode?section=civ&group=01001-02000&file=1708-1725>

California AED Regulations for Lay Rescuers

- (NEW) Revised 2008 Regulation California Code of Regulations, Title 22, Division 9, Prehospital Emergency Medical Services, Chapter 1.8. Public Access Automated External Defibrillator Regulations,
http://www.emsa.ca.gov/def_comm/2008032609C.asp;
(Final PAD Regulation for Lay Rescuers is anticipated to become law by 6-30-08)
- (CURRENT) Revised 2003 Regulation - California Code of Regulations, Title 22, Division 9, Chapter 1.8 Training Standards and Utilization of Use of the Automated External Defibrillator by Non-Licensed or Non-Certified Personnel,
<http://government.westlaw.com/linkedslice/default.asp?SP=CCR-1000&SPC=Timeout>

EMS 2003 Automated External Defibrillator Regulatory Information - Inconsistencies between the Layperson AED Regulation and California statute (Note: This is why the regulations were revised).

http://www.emsa.cahwnet.gov/legislation/aed_memo.doc